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Dated: September 4, 2009

Signature: Valerie Cohen  
(Valerie Cohen)

PATENT  
Docket No. 223002010005



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Michael HOUGHTON et al.

Serial No.: 09/884,456

Filing Date: June 18, 2001

For: HEPATITIS C VIRUS PROTEASE

Confirmation No.: 1937

Group Art Unit: 1656

Examiner: W. Moore

**INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. § 1.97 AND § 1.98**

MS RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Copies of the documents are also submitted herewith. The Examiner is requested to make these documents of record.

A) Applicants would like to bring to the attention of the Examiner the following remarks:

1. Applicants point out that Reference Nos. 71-99, and 372 have not been used in the PTO Form 1449 submitted herewith.

2. Applicants have been unable to locate a more readable copy of the document cited at Ref. No. 953 as Letter from A. Gorbalenya to H.-J. Thiel dated December 1990, Ex. 518 at 01/25/00 deposition of A. Gorbalenya. Applicants further note that this document was discussed at page 12 of the Transcript of the Deposition of A. Gorbalenya (Document No. 947).

3. Applicants note that they do not know whether the documents cited at Ref. Nos. 1053, 1082, and 1086 are published, and thus qualify as "printed publications". Applicants have included these documents on the PTO Form 1449 submitted herewith in the interest of making the disclosure as complete as possible.

4. Applicants note that they have made an effort to obtain information showing the date of the disclosure and/or the availability of the documents numbered 401, 402, 421, 466, 488, 533, 607, 608, 656, 702, 711, 729, 770, 805, 825, 831, 855, 1012, 1014, and 1029. As a result of these efforts, Applicants believe they have identified the following information relating to the publication and/or public presentation of these documents.

(a) Document nos. 401 and 729 are abstracts submitted for a meeting titled "Proteolytic Enzymes and Inhibitors in Biology and Medicine," held March 25-31, 1996, at Keystone CO. This meeting is after the effective filing date of the patent application.

(b) Document nos. 402, 466, 608, 825, and 855 are abstracts submitted for the 4th International Meeting on Hepatitis C Virus and Related Viruses, Molecular Virology and Pathogenesis, held March 6-10, 1997, in Kyoto, Japan. This meeting is after the effective filing date of the patent application.

(c) Document no. 1012 is an abstract submitted for the Meeting of the International Society for Antiviral Research and the Tenth International Conference on Antiviral Research,

Atlanta, Georgia, April 6-11, 1997; and published in Antiviral Res. 34(2):pA92 (1997). This meeting is after the effective filing date of the patent application.

(d) Document nos. 1014 and 1029 are abstracts submitted to ISVHLD-The 8th Triennial International Symposium on Viral Hepatitis and Liver Disease at Tokyo Japan from May 10-14, 1993. This meeting is after the effective filing date of the patent under examination.

(e) Document nos. 421, 488, 533, 607, 656, 702, 770, 805, and 831 are abstracts submitted for the 2nd International Meeting on Hepatitis C and Related Viruses, held July 31-August 5, 1994 in San Diego, California. This meeting is after the effective filing date of the patent application.

**B)** For the Examiner's convenience, Applicants have grouped the documents cited on the attached Form PTO-1449 into the categories outlined below.

1. Documents made of record in the prosecution and/or reexamination (where applicable) of the following U.S. patents and co-pending U.S. patent applications related to the present application:

U.S. Patent Nos. 5,585,258 ("258 patent") and Reexamination Certificate No. 5,585,258C1 issued on January 15, 2002; 5,597,691 ("691 patent") and Reexamination Certificate No. 5,597, 691C1 issued on December 11, 2001; 5,371,017 ("017 patent"); 5,885,799; and 5,712,145; and U.S. Patent Application Serial Nos. 09/253,230 and 09/253,675:

Ref. Nos. 1-70, 115, 117, 120, 123, 126, 127, 142, 143, 148, 149, 157, 158, 163, 209, 271, 318, 336, 340, 341, 342, 353, 360, 384, 389, 392, 403, 413, 414, 415, 442, 448, 470, 471, 473, 475, 485, 486, 502, 507, 510, 523, 544, 551, 573, 574, 576, 583, 589, 625, 659, 661, 666, 671, 694, 697, 706, 712, 719, 722, 732, 733, 751, 755, 756, 757, 780, 781, 787, 788, 796, 797, 798, 799, 806, 810, 813, 864, 867, 869, 870, 904, 915, 918, 999, 1001, 1003, 1009, 1011, 1022, 1024, 1027, 1044, 1049, and 1090-1096.

Applicants note that Reexamination Certificates confirming the patentability of all claims of the '258 patent and the '691 patent issued on January 15, 2002, and on December 11, 2001, respectively. The '017 patent is presently under reexamination.

2. Documents made of record in the prosecution of the following foreign counterparts to the present patent application:

PCT Application No. PCT/US91/02210; European Patent Application No 91908105; Japanese Patent Application No. 91507631; Polish Patent No. 169,273; Canadian Patent Application No. 2,079,105 (issued 6/13/2000); and Irish Patent Application No. 1129/91: Ref. Nos. 5-6, 46, 53, 142, 143, 194, 198, 200, 209, 219, 220, 226, 342, 434, 438, 576, 650, 713, and 1031.

3. Documents made of record in the prosecution of abandoned U.S. Patent Application Serial Nos. 07/505, 434, 07/680,358, 08/957,433, 08/116,048, and 08/254,496, and the International Search Report for PCT Application No. PCT/US91/02209 (WO publication No. 91/15596, Ref. No. 238), which name S. Rosenberg as inventor and have different claims but nearly identical specifications as the present application: Ref. Nos. 206, 207, 219, 220, 224, 576, 758, 975-979, 1094, and 1096.

Applicants note that those applications were abandoned. There are no pending applications and patents claiming priority to those patent applications. Pursuant to 37 CFR § 1.98(a)(2), Applicants have not provided copies of the specifications of those patent applications.

4. Material relating to the litigation of patents related to the present application, the '017, '691 and '258 patents, in the following actions in the U.S. District Court for the Northern District of California: *Chiron Corp. v. Agouron Pharmaceuticals, Inc.* (Civil Action No. C-98-2995 CW); *Chiron Corp. v. Eli Lilly & Co. and Vertex Pharmaceuticals, Inc.* (Civil Action No. C-98-02974 CW); and *Chiron Corp. v. Gilead Sciences, Inc.* (Civil Action No. C-98-2994 CW):

a) Agouron's Request for Reexamination of U.S. Patent No. 5,371,017 with appendix:

Ref. No. 926.

Applicants note that documents cited within Agouron's Request for Reexamination are included in Category 1, above, and Category 4(b), below.

- b) Agouron's Request for Reexamination of U.S. Patent No. 5,585,258 and appendix.  
Ref. No. 1058.

Applicants note that documents cited within Agouron's Request for Reexamination are included in Category 1, above, and Category 4(b), below.

- c) Documents relating to allegations by the defendants in Civil Action Nos. C-98-2994 CW, C-98-2995 CW, and C-98-02974 CW of invalidity, inequitable conduct or crime-fraud in connection with the patent under reexamination:

Ref. Nos. 316, 573, 902-917, 919-925, 927-929, 975, 999, 1001, 1003, 1009, 1011, 1022, 1024, 1027, 1040, 1044, 1049, and 1067.

Additionally, Applicants direct the Examiner to the following documents cited in those documents but not previously made of record:

Ref. Nos. 115, 117, 123, 128, 142, 143, 149, 157, 158, 160, 195, 209, 238, 269, 270, 271, 303, 305, 307, 316, 318, 336, 340, 341, 342, 353, 360, 384, 389, 392, 401, 403, 413, 414, 415, 418, 433, 442, 452, 470, 471, 473, 475, 482, 485, 486, 487, 502, 507, 510, 515, 544, 556, 573, 574, 583, 589, 624, 625, 650, 653, 659, 666, 671, 697, 706, 712, 719, 722, 732, 733, 740, 755, 756, 757, 762, 780, 781, 787, 788, 796, 797, 798, 799, 806, 813, 864, 869, 870, 904, and 915.

- d) Joint Claim Construction Statement Pursuant to Local Rule 16-11(b) in Civil Action No. C-98-02974 CW, with exhibits.  
Ref. No. 918.

- e) Written discovery responses by Chiron in Civil Action Nos. C-98-02974 CW, and C-98-2995 CW:  
Ref. Nos. 930-942.

Responses to written interrogatories and sub-parts thereof, or requests to admit and sub-arts thereof, that deny, state that there is insufficient information to answer or deny, or object, have not been included. If the Examiner wishes to consider this material, Applicants will submit it.

- f) Transcript of the deposition of Dr. Alexander Gorbalenya in the litigation of the '017, '258 and '691 patents (Civil Action Nos. C-98-2995 CW, C-98-2994 CW, and C-98-02974 CW), and exhibits marked at that deposition:  
Ref. Nos. 469, 721, and 946-960.

- g) Excerpts from the deposition testimony of Dr. Michael Houghton and Dr. Qui-Lim Choo in Civil Action Nos. C-98-2995 CW and C-98-02974 CW, pertaining to work by F. Bazan and A. Gorbalenya.  
Ref. No. 974.

- h) Notebook pages of Dr. Qui-Lim Choo referring to "NAR 17 1989, 3889" and "Russian findings on NS3 of flavivirus", respectively.  
Ref. Nos. 944 and 945.

- i) Excerpts from the deposition testimony of the inventors of the present application in response to questioning by the defendants concerning Dr. Kuo's involvement in the work leading to the '017, '258, and '691 patents.  
Ref. No. 973.

- j) Order re: Defendants Agouron's Motion For *In Camera* Review of Various Chiron Documents Pursuant to the Crime-Fraud Exception to the Attorney-Client Privilege.

Special Master Yanni, Case No. C-98-2974 CW, Related Action Nos. C-98-2994 CW and C-98-2995 CW. United States District Court, Northern District of California.

04/16/01.

Ref. No. 1059.

- k) Clerk's Notice Deeming Objection Denied. Case No. C-98-2974 CW, Related Action Nos. C-98-2994 CW and C-98-2995 CW. United States District Court, Northern District of California. 06/12/01.

Ref. No. 1060.

- l) Order re: Defendants Lilly and Vertex's Crime-Fraud Motion. Special Master Yanni, Case no. C-98-2974 CW, Related Action Nos. C-98-2994 CW and C-98-2995 CW. United States District Court, Northern District of California, 06/11/01.

Ref. No. 1061.

- m) Order Following *In Camera* Review of Chiron's Privileged Documents Pursuant to Agouron's Crime-Fraud Motion. Special Master Yanni, Case No. C-98-2974 CW, Related Action Nos. C-98-2994 CW and C-98-2995 CW. United States District Court, Northern District of California. 07/18/01.

Ref. No. 1089.

- n) Response to Chiron's Claim Chart Pursuant to Civil Local Rule 16-9(b) on U.S. Patent Nos. 5,371,017, 5,585,258 and 5,397,691 by Defendant Agouron Pharmaceuticals Incorporated. Chiron Corporation v. Agouron Pharmaceuticals, Inc.: Case No. C 98-2995 CW (PJH) (Related Cases C 98-9874 CW and C98-2994 CW). In the United States District Court, Northern District of California, Oakland Division, 67 pages. (08/04/1999).

Ref. No. 2, 5, 10-11, 25, 37, 45-46, 53, 58, 68, 149, 157-158, 195, 473, 475, 486, 502, 507, and 1054.

- o) Joint Response to Chiron's Claim Chart Pursuant to Civil Local Rule 16-9(b) on U.S. Patent Nos. 5,371,017, 5,585,258 and 5,397,691 by Defendants Eli Lilly and Company and Vertex Pharmaceuticals Incorporated. Chiron Corporation v. Eli Lilly and Company, and Vertex Pharmaceuticals Inc.: Case No. C 98-2974 (Related Action Nos. C 98-2994 CW and C 98-2995 CW). In the United States District Court, Northern District of California, Oakland Division, 32 pages.

Ref. No. 1-6, 9-15, 17-24, 26-70, 114, 117, 123, 128, 270, 318, 336, 340, 341-342, 353, 360, 384, 389, 403, 442, 470-471, 485, 544, 574, 589, 626, 659, 666, 719, 733, 780, 796-799, 806, 864, 869-870, 1001, 1003, 1009, 1027, 1044, 1090-1091, and 1094-1096.

5. Documents relating to the inventive entity for U.S. Patent No. 5,350,671.

It has been contended in several proceedings that Daniel Bradley should have been listed as a joint inventor on that U.S. Patent. Applicants respectfully refer the Examiner to Ref. Nos. 961-972, which were made of record during the prosecution of U.S. Patent Application No. 08/103,961, which application matured into U.S. Patent No 5,350,671.

6. The remainder of the documents cited on the attached Form PTO-1449 relate to Hepatitis C Virus, RNA Viruses, Hepatitis C Virus Protease, Protease, or Protease Inhibitors.

C) Applicants note that it obtained the following citations from material relating to the litigation of the '017, '691 and '258 patents, in the following actions in the U.S. District Court for the Northern District of California: *Chiron Corp. v. Agouron Pharmaceuticals, Inc.* (Civil Action No. C-98-2995 CW); *Chiron Corp. v. Eli Lilly & Co. and Vertex Pharmaceuticals, Inc.* (Civil Action No. C-98-02974 CW); and *Chiron Corp. v. Gilead Sciences, Inc.* (Civil Action No. C-98-2994 CW). Applicants were unable to locate or obtain copies of documents corresponding to these citations:



Feinstone et al. "Studies on non-A, non-B hepatitis in chimpanzees and marmosets" 295-304; Mitsuya, U. (1996) "Excerpt from article re urea derivatives/HIV protease inhibitors"; Love RA, et al. (1996) "Review of two abstracts" *Hepatology*, Elsewhere 87:343-355; Anonymous (1992) "Testing & Treatment," Consensus on HCV, Advanced Therapeutics Communications; Physicians World Communications Group; Change et al., (1977) *Nature* 198:1056.

Applicants believe that the citations may be incorrect. Applicants have listed these citations in the interest of making the disclosure in this reexamination as complete as possible.

Applicants note that documents are included in this IDS which have publication dates subsequent to the effective filing date of the patent for which this reexamination was granted and, therefore, are not prior art. These documents have been cited during related foreign or U.S. prosecutions and have come to the attention of Applicants during related litigation. These documents are cited here simply in the interest of making this examination as complete as possible.

This Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☒ With the filing of a Request for Continued Examination under 37 C.F.R. § 1.114.
- ☐ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
  - ☐ A fee is required. A check in the amount of \* is enclosed.
  - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below; accordingly; no fee is believed to be due.

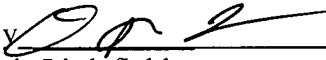
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
- ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below and a check in the amount of \* is enclosed.
- ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 223002010005. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: September 4, 2009

Respectfully submitted,

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